

**§ 177.2430 Polyether resins, chlorinated.**

Chlorinated polyether resins may be safely used as articles or components of articles intended for repeated use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The chlorinated polyether resins are produced by the catalytic polymerization of 3,3-bis(chloromethyl)-oxetane, and shall contain not more than 2 percent residual monomer.

(b) In accordance with good manufacturing practice, finished articles containing the chlorinated polyether resins shall be thoroughly cleansed prior to their first use in contact with food.

**§ 177.2440 Polyethersulfone resins.**

Polyethersulfone resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with food in accordance with the following prescribed conditions:

(a) For the purpose of this section, polyethersulfone resins are:

(1) Poly(oxy-*p*-phenylenesulfonyl-*p*-phenylene) resins (CAS Reg. No. 25667-42-9), which have a minimum number average molecular weight of 16,000.

(2) 1,1'-sulfonylbis[4-chlorobenzene] polymer with 4,4'-(1-methylethylidene)bis[phenol] (maximum 8 percent) and 4,4'-sulfonylbis[phenol] (minimum 92 percent) (CAS Reg. No. 88285-91-0), which have a minimum number average molecular weight of 26,000.

(3) In paragraphs (a)(1) and (a)(2) of this section, the minimum number average molecular weight is determined by reduced viscosity in dimethyl formamide in accordance with ASTM method D2857-70 (Reapproved 1977), "Standard Test Method for Dilute Solution Viscosity of Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, 1110 Vermont Ave. NW., suite 1200, Washington, DC, or at the Office of the Federal Register,

800 North Capitol St. NW., suite 700, Washington, DC.

(b) The basic resins identified in paragraphs (a)(1) and (a)(2) of this section may contain optional adjuvant substances described in § 174.5(d) of this chapter and the following:

List of substances	Limitations
Diphenylsulfone .....	Not to exceed 0.2 percent as residual solvent in the finished basic resin described in paragraph (a)(1) of this section.
Dimethyl sulfoxide .....	Not to exceed 0.01 percent as residual solvent in the finished basic resin described in paragraph (a)(1) of this section.
<i>N</i> -methyl-2-pyrrolidone .....	Not to exceed 0.01 percent as residual solvent in the finished basic resin described in paragraph (a)(2) of this section.

(c) The finished food-contact article, when extracted at reflux temperatures for 2 hours with the following four solvents, yields net chloroform-soluble extractives in each extracting solvent not to exceed 0.02 milligram per square inch of food-contact surface: distilled water, 50 percent (by volume) ethyl alcohol in distilled water, 3 percent acetic acid in distilled water, and *n*-heptane. (Note: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.)

(d) In accordance with good manufacturing practice, finished food-contact articles containing the polyethersulfone resins shall be thoroughly cleansed before their first use in contact with food.

[44 FR 34493, June 15, 1979, as amended at 47 FR 38885, Sept. 3, 1982; 49 FR 10111, Mar. 19, 1984; 50 FR 47211, Nov. 15, 1985; 60 FR 48648, Sept. 20, 1995]

**§ 177.2450 Polyamide-imide resins.**

Polyamide-imide resins identified in paragraph (a) of this section may be safely used as components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

(a) *Identity.* (1) For the purpose of this section the polyamide-imide resins are derived from the condensation reaction of substantially equimolar parts of trimellitic anhydride and *p,p'*-diphenylmethane diisocyanate.

(2) The polyamide-imide resins (CAS Reg. No. 31957-38-7) derived from the condensation reaction of equimolar parts of benzoyl chloride-3,4-dicarboxylic anhydride and 4,4'-diphenylmethanediamine.

(b) *Specifications.* (1) Polyamide-imide resins identified in paragraph (a)(1) of this section shall have a nitrogen content of not less than 7.8 weight percent and not more than 8.2 weight percent. Polyamide-imide resins identified in paragraph (a)(2) of this section shall have a nitrogen content of not less than 7.5 weight percent and not more than 7.8 weight percent. Nitrogen content is determined by the Dumas Nitrogen Determination as set forth in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), sections 7.016-7.020, which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(2) Polyamide-imide resins identified in paragraph (a)(1) of this section shall have a solution viscosity of not less than 1.200. Polyamide-imide resins identified in paragraph (a)(2) of this section shall have a solution viscosity of not less than 1.190. Solution viscosity shall be determined by a method titled "Solution Viscosity" which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(3) The polyamide-imide resins identified in paragraph (a)(1) of this section are heat cured at 600 °F for 15 minutes when prepared for extraction tests and the residual monomers: *p,p*-diphenylmethane diisocyanate should not be present at greater than 100 parts per million and trimellitic anhydride should not be present at greater than

500 parts per million. Residual monomers are determined by gas chromatography (the gas chromatography method titled "Amide-Imide Polymer Analysis—Analysis of Monomer Content," is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC).

(c) Extractive limitations are applicable to the polyamide-imide resins identified in paragraphs (a) (1) and (2) of this section in the form of films of 1 mil uniform thickness after coating and heat curing at 600 °F for 15 minutes on stainless steel plates, each having such resin-coated surface area of 100 square inches. The cured-resin film coatings shall be extracted in accordance with the method described in §176.170(d)(3) of this chapter, using a plurality of spaced, coated stainless steel plates, exposed to the respective food simulating solvents. The resin shall meet the following extractive limitations under the corresponding extraction conditions:

(1) Distilled water at 250 °F for 2 hours: Not to exceed 0.01 milligram per square inch.

(2) Three percent acetic acid at 212 °F for 2 hours: Not to exceed 0.05 milligram per square inch.

(3) Fifty percent ethyl alcohol at 160 °F for 2 hours: Not to exceed 0.03 milligram per square inch.

(4) *n*-Heptane at 150 °F for 2 hours: Not to exceed 0.05 milligram per square inch.

(d) In accordance with good manufacturing practice, those food contact articles, having as components the polyamide-imide resins identified in paragraph (a) of this section and intended for repeated use shall be thoroughly cleansed prior to their first use in contact with food.

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